Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

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Report Date:11/17/2008

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058812307 052000506 059501106	10/04/01 02/10/04 08/09/01	728 730 728	50 (1) 50 (1) 50 (1)	39(698) 32(691) 40(702)	52.9 51.1 52.3	Formamide Ginseng 5-(Hydroxymethyl)-2-furfural
				Fer	nale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058812307 052000506 059501106	10/03/01 02/09/04 08/08/01	727 729 727	50 (5) 50 (5) 50 (5)	38(692) 38(711) 39(694)	64.7 63.9 64.4	Formamide Ginseng 5-(Hydroxymethyl)-2-furfural

C131011: 110V2000

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 87

			Male				Female	
All Organs: Benign Tumors								
overall Incidence	Total	31/50 (62%) 111/150 (74%)	38/50 (76%) Mean 74%	42/50 (84%) SD 11.14%	Total	17/50 (34%) 76/150 (50.67%)	33/50 (66%) Mean 50.67%	26/50 (52%) SD 16.04%
All Organs: Malignant Tumors		20/50 /560/)	26/50 (520/)	26/50 (520/)		26/50 (520/)	45/50 (200/)	46/FO (220/)
verall Incidence	Total	28/50 (56%) 80/150 (53.33%)	26/50 (52%) Mean 53.33%	26/50 (52%) SD 2.31%	Total	26/50 (52%) 57/150 (38%)	15/50 (30%) Mean 38%	16/50 (32%) SD 12.17%
All Organs: Malignant and Benign Tu	ımors				•••••			
verall Incidence	Total	41/50 (82%) 136/150 (90.67%)	46/50 (92%) Mean 90.67%	49/50 (98%) SD 8.08%	Total	36/50 (72%) 112/150 (74.67%)	42/50 (84%) Mean 74.67%	34/50 (68%) SD 8.33%
All Organs: Hemangioma		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	2/50 (4%)
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	3/150 (2%)	Mean 2%	SD 2%
All Organs: Hemangiosarcoma					•••••			
verall Incidence	Total	3/50 (6%) 9/150 (6%)	4/50 (8%) Mean 6%	2/50 (4%) SD 2%	Total	2/50 (4%) 7/150 (4.67%)	0/50 (0%) Mean 4.67%	5/50 (10%) SD 5.03%
All Organs: Hemangiosarcoma or He	emangioma							
Overall Incidence	Total	5/50 (10%) 12/150 (8%)	5/50 (10%) Mean 8%	2/50 (4%) SD 3.46%	Total	2/50 (4%) 10/150 (6.67%)	1/50 (2%) Mean 6.67%	7/50 (14%) SD 6.43%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#All Organs: Histiocytic Sarcoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%
All Organs: Malignant Lymphoma: His or Undifferentiated Cell Ty		nphocytic, Mixed, NOS,						
verall Incidence	Total	2/50 (4%) 8/150 (5.33%)	4/50 (8%) Mean 5.33%	2/50 (4%) SD 2.31%	Total	10/50 (20%) 27/150 (18%)	9/50 (18%) Mean 18%	8/50 (16%) SD 2%
All Organs: Mesothelioma: Benign, Ma	alignant, NOS		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
ll Organs: Mesothelioma: Malignant	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Osteoma								
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 89

			Male		Female	
#All Organs: Osteosarcoma or Osteoma		0/50 (00%)	0/50 (00/) 0/50	(00()	0/50 (00/) 0/50 (00/)	0/50 /00/
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SD 0	(0%) % Total	0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Cortex: Adenoma					0/40 (00/) 0/50 (00/)	
Overall Incidence	Total	2/50 (4%) 8/149 (5.37%)	1/50 (2%) 5/49 Mean 5.4% SD 4.	(10%) .28% Total	0/49 (0%) 0/50 (0%) 0/149 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Cortex: Sarcoma					0(40 (00))	
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) 0/49 Mean 0% SD 0	(0%) % Total	0/49 (0%) 0/50 (0%) 0/149 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Medulla: Pheochromocytoma Benign		0/50 (0%)		(0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
overall Incidence	Total	0/149 (0%)	Mean 0% SD 0	` '	1/150 (0.67%) Mean 0.67%	SD 1.15%
Adrenal Medulla: Pheochromocytoma Comple	ex					
overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) 0/49 Mean 0% SD 0	(0%) % Total	0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Medulla: Pheochromocytoma Maligna					0/50 (00/) 0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 1/149 (0.67%)	0/50 (0%) 0/49 Mean 0.67% SD 1.	(0%) .15% Total	0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 90

			Male				Female	
Adrenal Medulla: Pheochromocytoma: Benigr	n, Complex	x, Malignant, NOS 1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Bone Marrow: Hemangiosarcoma		0/50 (00()	0/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/40 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Bone Marrow: Mast Cell Tumor Malignant		0/50 (004)	0/50 (00/)			0/50 (00)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Bone: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (00()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/30 (0%)	Mean 0%	0/50 (0%) SD 0%
Bone: Osteoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Bone: Osteosarcoma		0/50 (00)	0/50 (00/)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 91

			Male				Female	
#Bone: Osteosarcoma or Osteoma		2/52 (22)		2(72 (224)				2/22 (22)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Bone: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/30 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Meningioma Benign	•••••	0/50 (00/)	0/50 (00/)	0/50 (00/)	•••••	0/50 (00)	0/50 /00/	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Meningioma: Benign, Malign	ant, NOS	0/50 (00/)	0/50 (09/)	0/50 (0%)		0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Schwannoma Malignant		0/50 (00/)		0/50 (00/)		0/50 (00)	0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Clitoral/Preputial Gland: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (/09/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 92

			Male				Female	
*Clitoral/Preputial Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangioma	•••••							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Epididymis: Sarcoma		0/50 (00/.)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Esophagus: Squamous Cell Carcinoma	l	0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 /00/	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Eye: Sarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00())	0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Gallbladder: Adenoma		0/45 (0%)	0/49 (0%)			0/47 (0%)		
Overall Incidence	Total	0/43 (0%)	Mean 0%	0/49 (0%) SD 0%	Total	0/47 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%
#Harderian Gland: Adenoma		6/50 (12%)	11/50 (22%)	11/50 (22%)		4/50 (8%)	7/50 (14%)	7/50 (14%)
Overall Incidence	Total	28/150 (18.67%)	Mean 18.67%	SD 5.77%	Total	18/150 (12%)	Mean 12%	SD 3.46%
#Harderian Gland: Carcinoma		0/50 (49()	4/50 (00/)	2/50 (09/)		4/50 (00()	0/50 (00()	0/50 (00/)
Overall Incidence	Total	2/50 (4%) 6/150 (4%)	1/50 (2%) Mean 4%	3/50 (6%) SD 2%	Total	4/50 (8%) 4/150 (2.67%)	0/50 (0%) Mean 2.67%	0/50 (0%) SD 4.62%
#Harderian Gland: Carcinoma or Adenoma		7/50 (4.40())	40/50 (040/)	40/50 (00%)		0/50 (400)	7/50 (4.40)	7/50 (4.40()
Overall Incidence	Total	7/50 (14%) 32/150 (21.33%)	12/50 (24%) Mean 21.33%	13/50 (26%) SD 6.43%	Total	8/50 (16%) 22/150 (14.67%)	7/50 (14%) Mean 14.67%	7/50 (14%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Species: MICE Strain: B6C3F1 Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

	·		Male				Female	
#Harderian Gland: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Heart: Hemangioma		4/50 (00)	0/50 (00)	0/50 (00/)		0/50 (00)	0/50 (00)	0/50 (00)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Heart: Hemangiosarcoma		0/50 (004)	4/50 (00)	0/50 (00)	•••••	0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Heart: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
ntestine Large: Cecum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Intestine Large: Cecum: Carcinoma or Adenoma		0/50 (00)		4/50 (00)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Large: Cecum: Leiomyoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Polyp Adenomatous		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	0/50 (0%) SD 0%
#Intestine Large: Colon/Rectun Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Duodenum: Adenoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (09/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Duodenum: Carcinoma								(201)
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Duodenum: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Contract/Lab: All Laboratories Species: MICE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Intestine Small: Duodenum: Polyp Adenomatous		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Ileum: Hemangiosarcoma		0/50 (00()	0/50 (00/)	0/50 (00)		0/50 (00)	0/50 (00()	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Ileum: Polyp Adenomatous		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma		0/50 (0%)	0/50 (00/)	0/50 /00/		0/50 (00/)	0/50 (00()	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Jejunum: Carcinoma			0/50 (00/)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (004)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 97

			Male				Female	
Intestine Small: Jejunum: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
ntestine Small: Jejunum: Leiomyosarcoma	•••••							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
ntestine Small: Jejunum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
ntestine Small: Site Unspecific Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
ntestine Small: Site Unspecific Carcinoma	ed:							
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%
ntestine Small: Site Unspecific Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 98

Report Date:11/17/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

							Female	
#Intestine Small: Site Unspecified: Hemangiosarcoma								
	0/9	` ,	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence To		0 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspecified: Leiomyosarcoma					•••••			
•	0/9	50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence To	otal 0/15	0 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspecified: Polyp Adenomatous	0/:		0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence To		0 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma	0/:	50 (0%)	1/EO (29/)	0/50 (09/)		0/50 (0%)	1/50 (29/)	0/50 (0%)
Overall Incidence To		50 (0%) 0 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
*Islets, Pancreatic: Carcinoma								0/50 /00/
Overall Incidence To	0/9 otal 1/15	50 (0%) 0 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma		-0 (00()	0/50 (404)	0/50 (00()	•••••	0/50 (00()	4/50 (00)	0/50 (00/)
Overall Incidence To	0/9 otal 2/15	50 (0%) 0 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 99

			Male	Female
Kidney: Renal Tubule: Adenoma				
		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
idney: Renal Tubule: Carcinoma				
		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
idney: Renal Tubule: Carcinoma or Adenoma				
		0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
iver: Cholangiocarcinoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
ravall Incidence	Total	(,	` ,	
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
iver: Fibrous Histiocytoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
ver: Hemangioma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 100 Report Date:11/17/2008

Species: MICE Strain: B6C3F1 Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Liver: Hemangiosarcoma		4/50 (00()	0/50 (400)	4/50 (00)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 4/150 (2.67%)	2/50 (4%) Mean 2.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Liver: Hepatoblastoma		4/50 (20/)	4/50 (20/)	1/50 (20()		0/50 (00/)	0/50 (09/)	4/50 (20/)
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
*Liver: Hepatocellular Adenoma		04/50 (490()	24/50 (699()	22/50 (66%)		C/50 (400/)	04/50 (40%)	4.4/50 (000/)
Overall Incidence	Total	24/50 (48%) 91/150 (60.67%)	34/50 (68%) Mean 60.67%	33/50 (66%) SD 11.02%	Total	6/50 (12%) 41/150 (27.33%)	21/50 (42%) Mean 27.33%	14/50 (28%) SD 15.01%
*Liver: Hepatocellular Carcinoma	••••	45/50 (000)	44/50 (0004)	44/50 (000()		4/50 (004)	0/50 (404)	0/50 /40/
Overall Incidence	Total	15/50 (30%) 40/150 (26.67%)	14/50 (28%) Mean 26.67%	11/50 (22%) SD 4.16%	Total	4/50 (8%) 8/150 (5.33%)	2/50 (4%) Mean 5.33%	2/50 (4%) SD 2.31%
*Liver: Hepatocellular Carcinoma o	r Hepatobl				•••••			
Overall Incidence	Total	16/50 (32%) 42/150 (28%)	14/50 (28%) Mean 28%	12/50 (24%) SD 4%	Total	4/50 (8%) 9/150 (6%)	2/50 (4%) Mean 6%	3/50 (6%) SD 2%
*Liver: Hepatocellular Carcinoma o	r Hepatoce	ellular Adenoma 33/50 (66%)	39/50 (78%)	39/50 (78%)	•••••	9/50 (18%)	23/50 (46%)	14/50 (28%)
Overall Incidence	Total	111/150 (74%)	Mean 74%	SD 6.93%	Total	46/150 (30.67%)	Mean 30.67%	SD 14.19%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 101 Report Date:11/17/2008

Species: MICE **Strain:** B6C3F1

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Liver: Hepatocellular Carcinoma, H Hepatoblastoma	epatocell							
Overall Incidence	Total	34/50 (68%) 112/150 (74.67%)	39/50 (78%) Mean 74.67%	39/50 (78%) SD 5.77%	Total	9/50 (18%) 47/150 (31.33%)	23/50 (46%) Mean 31.33%	15/50 (30%) SD 14.05%
*Liver: Hepatocholangiocarcinoma		4/50 (00)						
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Liver: Ito Cell Tumor Benign	••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Liver: Sarcoma		0/50 (0%)	0/50 (09/)	0/50 (09/)		0/50 /09/	0/50 (09/)	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Lung: Adenoma	••••	0/50 (0%)	0/50 (09/)	0/50 (09/)		0/50 (00/)	0/50 (09/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 102

			Male				Female	
Lung: Alveolar/Bronchiolar A	denoma	40/50 (200/)	0/50 /400/	40/50 (200/)		4/EQ (99/\	G/EQ (4.20/.)	2/50 (40()
Overall Incidence	Total	10/50 (20%) 29/150 (19.33%)	9/50 (18%) Mean 19.33%	10/50 (20%) SD 1.15%	Total	4/50 (8%) 12/150 (8%)	6/50 (12%) Mean 8%	2/50 (4%) SD 4%
_ung: _ung: Alveolar/Bronchiolar C								
verall Incidence	Total	6/50 (12%) 16/150 (10.67%)	3/50 (6%) Mean 10.67%	7/50 (14%) SD 4.16%	Total	2/50 (4%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	1/50 (2%) SD 1.15%
ung: Alveolar/Bronchiolar C Adenoma	carcinoma or Al	veolar/Bronchiolar 16/50 (32%)	12/50 (24%)	16/50 (32%)		5/50 (10%)	7/50 (14%)	3/50 (6%)
verall Incidence	Total	44/150 (29.33%)	Mean 29.33%	SD 4.62%	Total	15/150 (10%)	Mean 10%	SD 4%
ung: Fibrosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
ung: Fibrous Histiocytoma		0/50 (00/)	0/50 (09/)	0/50 (09/)		0/50 (00/)	0/50 /00/	0/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
ung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/30 (0%)	0/50 (0%) Mean 0%	0/30 (0%) SD 0%	Total	0/150 (0%)	0/30 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

511. 140V2000

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 103

			Male				Female	
Lung: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lymph Node: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node: Hemangioma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 /00/	0/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
ymph Node: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
ymph Node: Sarcoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lymph Node, Bronchial: Hemangiosarcoma		0/50 (00)	0/50 (00()	0/50 (0%)		0/50 (00/)	0/50 /00/	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

11: 14072000

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 104

			Male				Female	
Lymph Node, Mandibular: Fibrous Histiocytoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
:								
Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Mast Cell Tumor Malignant		0/50 (00/)	4/50 (004)	0/50 (001)		0/50 (00/)	0/50 (00/)	0/50 (00/)
overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lymph Node Messylvie								
Lymph Node, Mesenteric: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
						3,100 (0,0)		
Lymph Node, Mesenteric: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 105

Report Date:11/17/2008

Contract/Lab: All Laboratories Species: MICE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Mammary Gland: Adenoacanthoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma	•••••	0.700 (001)	(00)	0.70		(20)	(70)	(201)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Mammary Gland: Carcinoma		0/50 /00()	0/50 /00/	0/50 (00)		0/50 /40/	0/50 (00/)	4/50 (00())
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 3/150 (2%)	0/50 (0%) Mean 2%	1/50 (2%) SD 2%
#Mammary Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%
#Mammary Gland: Fibroadenoma	•••••	0/50 (00/)	0/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 /09/	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Mammary Gland: Fibroma, Fibroadenoma o			-((201)				(201)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma	, Carcinoma, o			2(72 (224)		2/20 (10)		(201)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%
#Mocontory								•••••
#Mesentery: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Mesentery:								
Hemangioma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Nose:		•••••						
Hemangioma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
		, ,				, ,		

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 106

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 107

			Male				Female	
Nose:								
Mast Cell Tumor Maligi	nant	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	0/30 (0 <i>%</i>) Mean 0%	0/49 (0 <i>%</i>) SD 0%
		` ,				,		
Oral Cavity (Oral Mucosa, Papilloma Squamous o		, , ,						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, Squamous Cell Carcing		nx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/450 (00/)	Man 00/	OD 00/	T-1-1	4/450 (0.070/)	Mana 0.070/	SD 1.15%
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	3D 1.1376
	, Tongue, Phary	nx, Tooth, Gingiva): Squamous, or			lotal			
Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma	, Tongue, Phary	nx, Tooth, Gingiva):		0/50 (0%) SD 0%	Total	0/50 (0.67%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Oral Cavity (Oral Mucosa, Squamous Cell Carcino	, Tongue, Phary oma, Papilloma Total	nx, Tooth, Gingiva): Squamous, or 0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma verall Incidence Oral Mucosa:	, Tongue, Phary oma, Papilloma Total	nx, Tooth, Gingiva): Squamous, or 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma verall Incidence Oral Mucosa: Squamous Cell Carcino verall Incidence	, Tongue, Phary oma, Papilloma Total oma	nx, Tooth, Gingiva): Squamous, or 0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)	Total	0/50 (0%) 1/150 (0.67%) 0/50 (0%)	0/50 (0%) Mean 0.67% 0/50 (0%)	1/50 (2%) SD 1.15% 0/50 (0%)
Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma verall Incidence Oral Mucosa: Squamous Cell Carcino	, Tongue, Phary oma, Papilloma Total oma	nx, Tooth, Gingiva): Squamous, or 0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)	Total	0/50 (0%) 1/150 (0.67%) 0/50 (0%)	0/50 (0%) Mean 0.67% 0/50 (0%)	1/50 (2%) SD 1.15% 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female	
*Ovary: Cystadenoma		1/50 (2%)	7/50 (14%)	3/50 (6%)
Overall Incidence	Total	11/150 (7.33%)	Mean 7.33%	SD 6.11%
*Ovary: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Benign Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Ovary: Granulosa Cell Tumor Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%
*Ovary: Hemangioma		0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 109

Report Date:11/17/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male	Female
*Ovary: Hemangiosarcoma Overall Incidence	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Ovary: Leiomyosarcoma Overall Incidence	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Ovary: Luteoma Overall Incidence	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Ovary: Teratoma Benign Overall Incidence	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Ovary: Teratoma Malignant Overall Incidence	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Ovary: Tubulostromal Adenoma Overall Incidence	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Vehicle: WATER

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories Species: MICE Route: GAVAGE

Length of Study: CHRONIC

Page: 110

			Male				Female	
Pancreas: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%	SD 0%
ancreas: Carcinoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/40 (00/)	0/50 (004)	0/40 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
verali ilicidence		, ,				, ,		
ancreas: Carcinoma or Adenoma								
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
·····		, ,				,		
ituitary Gland: Pars Distalis Adenoma								
		1/50 (2%)	1/50 (2%)	0/48 (0%)		3/50 (6%)	1/50 (2%)	2/49 (4%)
verall Incidence	Total	2/148 (1.35%)	Mean 1.33%	SD 1.15%	Total	6/149 (4.03%)	Mean 4.03%	SD 2%
ituitary Gland: Pars Distalis Carcinoma								
		1/50 (2%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%	Total	0/149 (0%)	Mean 0%	SD 0%
				•••••	•••••			
ituitary Gland: Pars Distalis Carcinoma or Adenoma	or Unspecif		4/50 (00/)	0/40 /00/		0/50 (00/)	4/50 (00()	0/40 /40/
		2/50 (4%) 3/148 (2.03%)	1/50 (2%) Mean 2%	0/48 (0%) SD 2%	Total	3/50 (6%) 6/149 (4.03%)	1/50 (2%) Mean 4.03%	2/49 (4%) SD 2%
verall Incidence	Total							

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: WATER

			Male				Female	
Pituitary Gland: Pars Intermo Adenoma	edia:							
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	1/50 (2%) 4/149 (2.68%)	1/50 (2%) Mean 2.69%	2/49 (4%) SD 1.2%
Pituitary Gland: Pars Interme Carcinoma or Adenoma	edia:	2/22 (22)	0.770 (001)	2/12 /22/		(201)	(00)	
overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	1/50 (2%) 4/149 (2.68%)	1/50 (2%) Mean 2.69%	2/49 (4%) SD 1.2%
Prostate: Adenoma		0/50 (/0/)	0/50 (09/)	0/50 (09/)	•••••			
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
rostate: Carcinoma or Adenoma								
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
rostate: Hemangioma		0/50 (00/)	0/50 (00()	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
Salivary Glands: Carcinoma		0/50 (00/)	0/50 (09/)	0/50 (0%)	•••••	0/40 (00/)	0/50 (09/)	0/40 (09/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

511. 140V2000

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 112

			Male	Female
Salivary Glands: Carcinoma or Adenoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/49 (0%) 0/50 (0%) 0/49 (0%) Total 0/148 (0%) Mean 0% SD 0%
		` ,		
Salivary Glands: Mast Cell Tumor Malignant		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/49 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/148 (0%) Mean 0% SD 0%
Seminal Vesicle: Adenoma		2/52 (224)	272 (201)	
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	
		` ,		
Skeletal Muscle: Fibrosarcoma				
	Tatal	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
Skeletal Muscle: Hemangiosarcoma		•••••		
-		0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 1/150 (0.67%) Mean 0.67% SD 1.15%
keletal Muscle: Myxosarcoma				
	.	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date:11/17/2008

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma or R								
-	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Sarcoma					•••••			
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Adenoma or Ba	asosquamou		0(50 (00))	0(50 (00))		0(50 (004)	0/50 (004)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Adenoma, Basa Trichoepithelioma		Tumor Benign, or						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
word! Incidence	Total	` ,	` '	` ,	Total	` '	` ,	` ,
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date:11/17/2008

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Basal Cell Carcinoma or Bas NOS)	osquamo	us Tumor (malignant or						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Basal Cell Carcinoma, Basal Tumor (benign, malignant or	Cell Ader	noma, Basosquamous	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		, ,				, ,		
Basal or Sq. Cell Carcinoma, or B), Basal Cell Adenoma, A Papilloma, Keratoacanthoma	Adenoma,	Papilloma, Sq	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Basosquamous Tumor Beni		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Fibroma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcoma, Saro Fibrous Histiocytoma	coma, Myx		4/50 (00())	0/50 (00/)		4/50 (00/)	4/50 (00)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 5/150 (3.33%)	4/50 (8%) Mean 3.33%	0/50 (0%) SD 4.16%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 115

			Male				Female	
Skin: Fibrosarcoma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 3.46%
Skin: Fibrosarcoma, Sarcoma, M Histiocytoma	Myxosarcom	na, or Fibrous						
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 5/150 (3.33%)	4/50 (8%) Mean 3.33%	0/50 (0%) SD 4.16%
Skin: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin: Hemangioma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Hemangiosarcoma		0/50 (00/)	0/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Liposarcoma		0/50 (00/)	0/50 (0%)	0/50 (00)		0/50 (00/)	0/50 (0%)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 116

			Male				Female	
Skin: Myxosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Neural Crest Tumor		2/22 (22)	(00)	(20)		(201)	0.770 (000)	(00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Neurofibrosarcoma or S	chwannoma (1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	Mean 1.33%	0/50 (0%) SD 2.31%
Skin: Neurofibrosarcoma, Neu malignant or NOS)	ırofibroma, or	Schwannoma (benign,						
verall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%
Skin: Osteosarcoma		0/50 (00()	0/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 (00)
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incide

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 117

			Male				Female	
#Skin: Schwannoma Malignan	t	0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
Skin: Squamous Cell Carcino	ma	0/50 (00)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Squamous Cell Carcino Basosquamous Tumor			0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papillon		0/50 (00)						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Squamous Cell Papillon	na or Papilloma	a 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
Skin:		Squamous Cell						
Squamous Cell Papillon Carcinoma or Keratoaca	antnoma							

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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ups Report Date:11/17/2008

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			M	lale				Female	
#Skin: Squamous Cell Papilloma,	Papilloma,			()					
		0/50 (09	,	(0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)		n 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Trichoepithelioma									0/50 (00/)
N	T-1-1	0/50 (09	,	(0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)		n 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Sebaceous Gland: Adenoma									
		0/50 (09	,	(0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)		n 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Sebaceous Gland: Carcinoma									
N	T-1-1	0/50 (09	,	(0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Meai	n 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Sebaceous Gland: Carcinoma or Adenoma									
		0/50 (09	%) 0/50	(0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mea	n 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Spinal Cord: Meningioma Malignant									
	.	0/50 (09	,	(0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mear	n 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 119

			Male		Female
Spleen: Fibrous Histiocytoma		0/50 (00()	0/50 (00/)	0/50 (00/)	0/50 (00) 0/40 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/149 (0%)	0/50 (0%) 0/49 (0%) Mean 0% SD 0%
Spleen: Hemangioma	•••••	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%) 0/49 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	Total 1/149 (0.67%)	1/50 (2%) 0/49 (0%) Mean 0.67% SD 1.15%
Spleen: Hemangiosarcoma		0/50 /40/	4/50 (00() 4/50 (00()	4/50 (000)	0/50 (00) 4/40 (00)
Overall Incidence	Total	2/50 (4%) 4/150 (2.67%)	1/50 (2%) 1/50 (2%) Mean 2.67% SD 1.15%	1/50 (2%) Total 5/149 (3.36%)	0/50 (0%) 4/49 (8%) Mean 3.39% SD 4.25%
Stomach, Forestomach: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%)	Mean 0% SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma					
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma o	or Papillon	na Squamous 0/50 (0%)	1/50 (2%) 2/50 (4%)	1/50 (2%)	0/50 (0%) 2/50 (4%)
Overall Incidence	Total	3/150 (2%)	Mean 2% SD 2%	Total 3/150 (2%)	Mean 2% SD 2%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 120

			Male				Female	
#Stomach, Forestomach: Squamous Cell Papilloma								
Overall Incidence	Total	0/50 (0%) 3/150 (2%)	1/50 (2%) Mean 2%	2/50 (4%) SD 2%	Total	1/50 (2%) 3/150 (2%)	0/50 (0%) Mean 2%	2/50 (4%) SD 2%
#Stomach, Glandular: Adenoma	•••••	0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Stomach, Glandular: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Stomach, Glandular: Carcinoma or Adenoma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Testes: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Testes: Hemangiosarcoma		0/50 (00)	0/50 (00/)	0.50 (00)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 121

			Male				Female	
Thymus: Thymoma Malignant								
Overall Incidence	Total	0/47 (0%) 0/137 (0%)	0/47 (0%) Mean 0%	0/43 (0%) SD 0%	Total	0/49 (0%) 0/144 (0%)	0/48 (0%) Mean 0%	0/47 (0%) SD 0%
Thymus: Thymoma: Benign, Malignant	, NOS	0/47 (0%)	0/47 (0%)	0/43 (0%)		0/49 (0%)	0/48 (0%)	0/47 (0%)
Overall Incidence	Total	0/47 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%
Гhyroid Gland: Adenoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/146 (0%)	0/49 (0%) Mean 0%	0/48 (0%) SD 0%
hyroid Gland: C-Cell: Carcinoma		0/50 (00()	0/50 (0%)	0/50 (0%)		0/40 (00/)	0/40 (00/)	0/40 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/146 (0%)	0/49 (0%) Mean 0%	0/48 (0%) SD 0%
hyroid Gland: C-Cell: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/146 (0%)	0/49 (0%) Mean 0%	0/48 (0%) SD 0%
Гhyroid Gland: Follicular Cell: Adenoma								
Overall Incidence	Total	0/50 (0%) 3/150 (2%)	1/50 (2%) Mean 2%	2/50 (4%) SD 2%	Total	2/49 (4%) 3/146 (2.05%)	0/49 (0%) Mean 2.05%	1/48 (2%) SD 2.04%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 122 Report Date:11/17/2008

Species: MICE Strain: B6C3F1 Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male	Female			
*Thyroid Gland: Follicular Cell: Carcinoma							
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67% SD 1.15%	0/49 (0%) 0/49 (0%) 0/48 (0%) Total 0/146 (0%) Mean 0% SD 0%			
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma		4/50 (20/)	4/50 /00/\ 0/50 /40/\	2/40 (497) 0/40 (097) 4/49 (097)			
Overall Incidence	Total	1/50 (2%) 4/150 (2.67%)	1/50 (2%) 2/50 (4%) Mean 2.67% SD 1.15%	2/49 (4%) 0/49 (0%) 1/48 (2%) Total 3/146 (2.05%) Mean 2.05% SD 2.04%			
#Tissue NOS: Carcinoma		0/50 (00/)	0/50 /00/) 0/50 /00/)	0/50 (00() 0/50 (00() 0/50 (00()			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%			
#Tissue NOS: Hemangiosarcoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%			
#Tissue NOS: Schwannoma Malignant		0/50 (004)	0/50 (00)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%			
#Tongue: Squamous Cell Carcinoma		0/50 (00/)	0/50 (00/) 0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 123
Report Date:11/17/2008

Species: MICE Strain: B6C3F1 Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

		Male				Female			
#Tongue: Squamous Cell Carcinoma or Papilloma Squamous									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	
#Tongue: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%	
#Tooth: Odontoma	••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Hemangioma		4/50 (00/)	0/50 /00/)	0/50 (00/)		0/50 /00/)	0/49 (0%)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	
*Urinary Bladder: Hemangiosarcoma		(00)	(201)	(201)			2/12 (22)	(00)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	
*Urinary Bladder: Sarcoma		0/50 (0%)	0/50 (09/)	0/50 (09/)		0/50 (09/)	0/40 (/0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

M	ale	Fema	le
#Uterus: Adenoma		0/50 (0%) 0/50	(0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%) 0/30 0/150 (0%) Mean	` '
#Uterus: Carcinoma			
Overall Incidence	Total	0/150 (0%) Mean	
#Uterus: Hemangioma			
Overall Incidence	Total	,	(0%) 2/50 (4%) 1.33% SD 2.31%
#Uterus: Hemangiosarcoma			
Overall Incidence	Total	0/50 (0%) 0/50 0/150 (0%) Mean	(0%) 0/50 (0%) 0% SD 0%
#Uterus:			
Leiomyoma Overall Incidence	Total	0/50 (0%) 0/50 0/150 (0%) Mean	(0%) 0/50 (0%) 0% SD 0%
#Uterus: Leiomyosarcoma		0/50 (00) 0/50	(00)
Overall Incidence	Total	0/50 (0%) 0/50 0/150 (0%) Mean	(0%) 0/50 (0%) 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male	Female				
#Uterus: Polyp Stromal		0/50 (0%)	0/50 (0%) 1/50 (2%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%			
#Uterus: Sarcoma Stromal		0/50 (0%)	0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%			
#Uterus: Sarcoma Stromal or Polyp Stromal		0/50 (0%)	0/50 (0%) 1/50 (2%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%			
#Uterus: Schwannoma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%			
#Vagina: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%			
#Vagina: Squamous Cell Papilloma		0/50 (00/)	0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: WATER

#Zymbal's Gland: Carcinoma		Male				Female			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
		` ,				` ,			
#Zymbal's Gland: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied